

# Why Toxicity Values Are in Flux: A Summary and Perspective on Recent IRIS Assessments

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# Role of Risk Assessment on Environmental Projects

- Used to determine whether site requires further study or remediation
- Used with regulatory values to determine cleanup levels
- Risk-based screening levels (aka PRGs, RBCs, RSLs)
  - ▶ Screen sites early in project lifecycle
  - ▶ Determine project quantitation limits



# Risk-Based Values Function of Toxicity and Exposure

$$\text{Risk} = \frac{\text{Intake}}{\text{Toxicity}}$$

↑ Toxicity = ↓ Criteria

- Tiered approach used to identify toxicity values for site risk assessments
- Integrated Risk Information System (IRIS)
- IRIS values also inform regulatory decisions (MCLs etc.)



# Emerging Contaminants (ECs)

- Are chemicals or materials of interest that are characterized by:
  - ▶ a perceived or real threat to human health or environment, and
  - ▶ there is no currently published health standard or there is an existing health standard, but the standard is evolving or being re-evaluated.

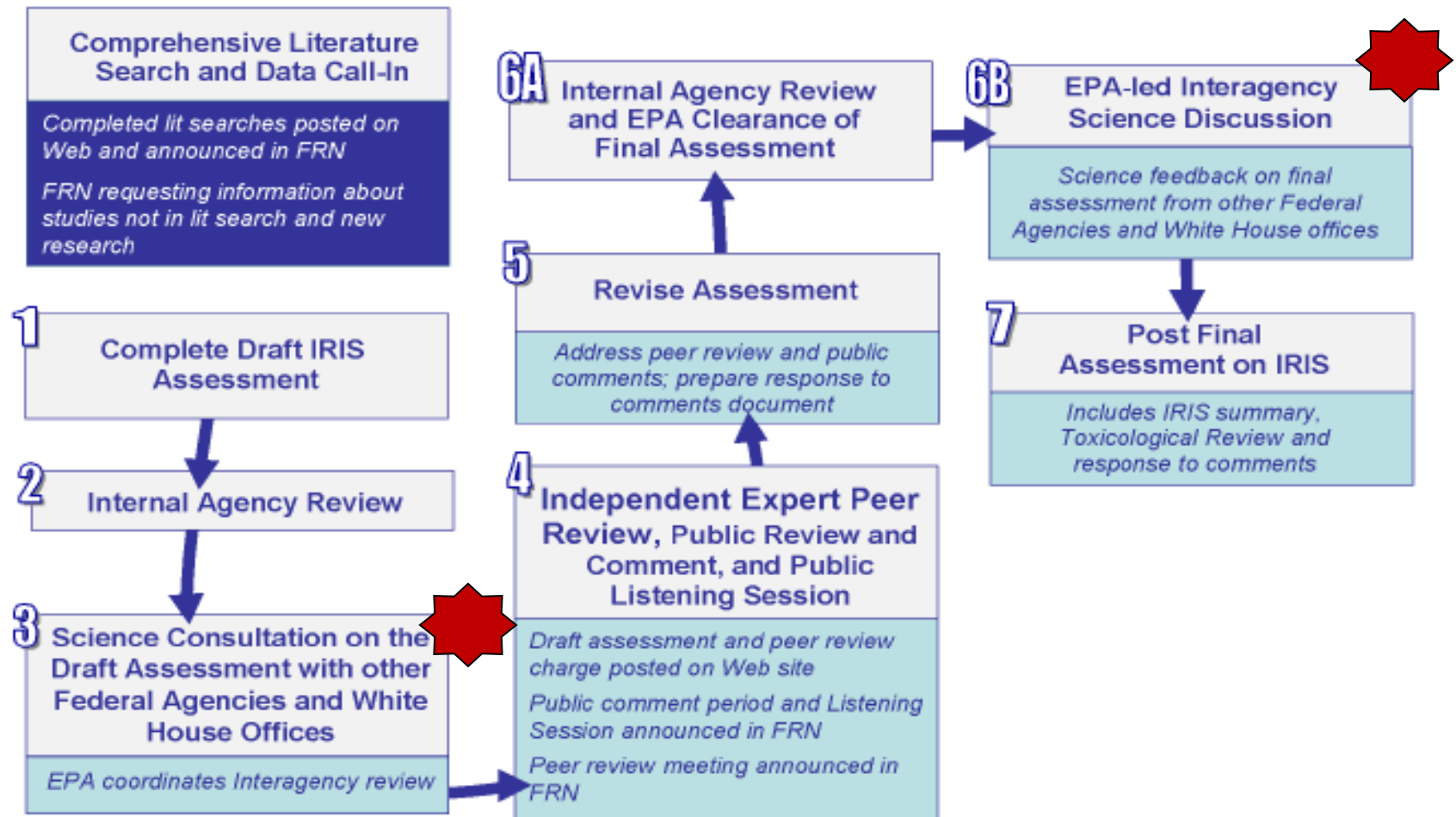
Source: “Initiation of Emerging Contaminants Characterization and Response Actions for Protection of Human Health” Issue Paper (ECOS & DoD Sustainability Workgroup, 2008)





# DoD Participation in IRIS Interagency Reviews

## *Assessment Development Process for New IRIS*



# Potential Changes in Risk Assessment of PAHs

- Relative potency factors used to assess carcinogenicity of PAHs – all set relative to benzo(a)pyrene
- EPA: “Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures”
  - ▶ Under review by EPA Science Advisory Board
- RPF approach retained but updated by new data/science



# Carcinogenic PAHs and Relative Potency Factors

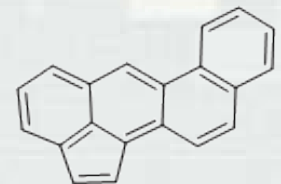
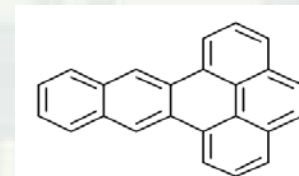
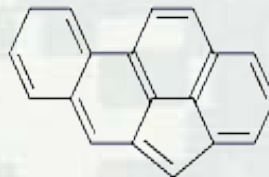
	Current RPF	Draft RPF
Benzo(a)pyrene	1	1
Benz(a)anthracene	0.1	0.2
Benzo(b)fluoranthene	0.1	0.5
Benzo(k)Fluoranthene	0.01	0.03
Chrysene	0.001	0.1
Dibenz(a,h)anthracene	1	6
Indeno(1,2,3-c,d)pyrene	0.1	0.07





# Additional PAHs from 2010 RPF Assessment

- Anthanthrene
- Benzo[g,h,i]perylene
- Benzo[j]fluoranthene
- Cyclopenta[c,d]pyrene
- Dibenzo[a,e]fluoranthene
- Dibenzo[a,e]pyrene
- Dibenzo[a,h]pyrene
- Dibenzo[a,i]pyrene
- Dibenzo[a,l]pyrene
- Fluoranthene
- Benz[b,c]aceanthrylene
- Benz[e]aceanthrylene
- Benz[j]aceanthrylene (60x)
- Benz[l]aceanthrylene
- Cyclopenta[d,e,f]chrysene
- Naphtho[2,3-e]pyrene



# Tetrachloroethylene

## Status: External Peer Review

- 1998 initiated
- June 2008 external review version released
- Nat'l Academy Review Feb 2006
- Current external (SAB) and public review

Risk-Based Screening Levels*			
	Res. Soil (mg/kg)	Res. Water Use (µg/L)	Indoor Air (µg/m <sup>3</sup> )
Current	0.55	0.11	0.41
New (draft)	0.293	0.179	0.122
Sources of current toxicity values include EPA IRIS, ATSDR and CalEPA. Lowest RSL target risk = $10^{-6}$ . Draft values not suitable for project use.			

# Trichloroethylene

## Status: External Peer Review

- IRIS values withdrawn late 1980s
- 2001 draft released
- 2006 NAS review
- 2009 re-released
- Lowest RSLs based on  $10^{-6}$  cancer risk

### Risk-Based Screening Levels\*

	Res. Soil (mg/kg)	Res. Water Use (µg/L)	Indoor Air (µg/m <sup>3</sup> )
Current	2.8	2	1.2
New (draft)	0.48	0.23	0.24
CalEPA source of current values. Lowest RSL target risk = $10^{-6}$ . Draft values not suitable for project use.			



# Dioxin

## Status: External Peer Review

- Assessment initiated in 1990
- Released for public and peer review 2010
- Using cancer toxicity values in this draft residential screening levels could be as low as 0.45 ppt dioxin toxicity equivalent (TEQ, for dioxin-like compounds)
- Current EPA policy recommends 1000 ppt
  - ▶ EPA may release an Interim PRG



# Hexavalent Chromium

## Status: External Peer Review

- Derives an oral slope factor using 2008 National Toxicology Program studies
- NTP studies also used to update noncancer ingestion value (3x change)
- Lowest RSLs based on  $10^{-6}$  cancer risk

### Risk-Based Screening Levels\*

	Res. Soil (mg/kg)	Res. Water Use (µg/L)
Old	2300	11
New (draft)	0.29	0.043
Draft values not suitable for project use. Cancer risk drives new RSLs.		



# Final IRIS Reference Dose for Cis-1,2-Dichloroethylene (September 2010)

- Oral noncancer reference dose (RfD) = 0.002 mg/kg-day; increased kidney weight
  - ▶ PPRTV used until this time
  - ▶ MCL = 70 µg/L
- No cancer toxicity values published

Risk-Based Screening Levels*		
	Residential Soil (mg/kg)	Residential Water Use (µg/L)
Old	780	370
New	156	73
Fold Change	5x	





# Final IRIS Reference Dose for Trans-1,2- Dichloroethylene (September 2010)

- Oral noncancer reference dose (RfD) = 0.02 mg/kg-day;
- Based on decreased antibody production by the spleen
- No change in RfD value, but change of critical effect
- MCL = 100 µg/L
- No cancer toxicity values published



# Final IRIS Values for 1,4-Dioxane (August 2010)

- Oral noncancer reference dose (RfD) = 0.03 mg/kg-day; Liver & kidney effects
  - ▶ Inhalation RfC will be developed in separate document
- Oral cancer slope factor (SF) = 0.1 mg/kg-day<sup>-1</sup>; Rodent liver tumors

Risk-Based Screening Levels*		
	Residential Soil (mg/kg)	Residential Water Use (µg/L)
Old	44.1	6.1
New	4.85	0.67
Fold Change	9x	



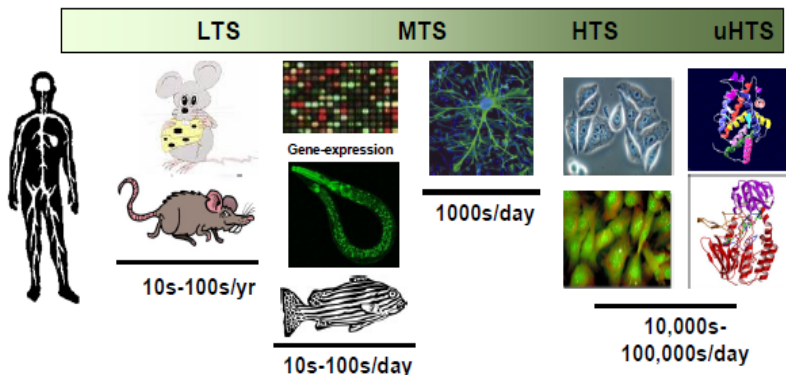
# Basis for Changes

- New study data
  - ▶ Sensitive measurements
- Science policy
  - ▶ Mutagenic mode action adjustment
  - ▶ Uncertainty factor application
  - ▶ Benchmark Dose
- Other impacts
  - ▶ Critical study selection
  - ▶ Linear low dose extrapolation



## High-Throughput Screening Assays

batch testing of chemicals for pharmacological/toxicological endpoints using automated liquid handling, detectors, and data acquisition



Human Relevance/  
Cost/Complexity

Throughput/  
Simplicity

Office of Research and Development  
National Center for Computational Toxicology

## The future!

### EPA Next Generation Risk Assessment

New technology will lead to greater capacity and speed. Interpretation of results is a challenge; studies underway to link known effects with screening assay data.

### Systems Exposure Science : Extending Network Analysis

Consider coupled networks spanning multiple levels of biological organization

